



## General

### Guideline Title

Hepatitis B virus.

### Bibliographic Source(s)

New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2013 Aug. 33 p. [79 references]

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2008 Jun. 23 p. [49 references]

## Recommendations

### Major Recommendations

The quality of evidence (I-III) and strength of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

#### What's New and Key Recommendations — August 2013 Update

##### Hepatitis B Virus (HBV) Vaccination in Human Immunodeficiency Virus (HIV)-Infected Patients

- Administer the HBV vaccination series to HIV-infected patients who are susceptible to HBV infection (see Figure 3 in the original guideline document)
- Alternative vaccination strategies may be considered for primary HBV vaccination, such as a three- or four-injection double-dose vaccination series or an accelerated HBV vaccination schedule of 0, 1, and 3 weeks. Do not administer the accelerated HBV vaccination schedule to patients with CD4 counts  $<500$  cells/mm<sup>3</sup>
- Test for hepatitis B surface antibody (anti-HBs) 1 to 2 months after administration of the last dose of the vaccination series
- Re-vaccinate with a double-dose vaccination series when HIV-infected patients do not respond to the primary HBV vaccination series (anti-HBs  $<10$  IU/L)

##### Treatment of HBV Infection in the Setting of HIV

- Strongly encourage HIV-infected patients with chronic HBV infection to initiate treatment for both viruses
- Initiate treatment with an antiretroviral therapy (ART) regimen that contains two agents that are also active against the patient's HBV strain, including tenofovir plus either lamivudine or emtricitabine

- Consult with a provider experienced in the treatment of hepatitis and HIV to determine an alternative anti-HBV regimen if first-line anti-HBV treatment with tenofovir plus lamivudine or entricitabine cannot be prescribed because of HBV resistance to any of these agents or the presence of renal insufficiency or fulminant hepatic disease
- Avoid discontinuation of either HBV or HIV treatment whenever possible and monitor serum alanine aminotransferase (ALT) levels closely if discontinuation of anti-HBV therapy is unavoidable

#### Monitoring HIV-Infected Patients with Chronic HBV Infection

- Monitor HIV/HBV co-infected patients according to the considerations listed in the Table 4 in the original guideline document
- Assess for the risk of hepatocellular carcinoma (HCC) in HIV-infected patients with chronic HBV infection according to standard guidelines (see Table 5 in the original guideline document)
- Perform surveillance for HCC among patients at high risk every 6 to 12 months according to standard guidelines (see the "Patients at Risk for HCC" section below)

#### Baseline Hepatic Evaluation and Screening for HBV Infection

##### Baseline Hepatic Evaluation

As part of the baseline assessment of HIV-infected patients, clinicians should evaluate liver function, including serum aspartate aminotransferase (AST) and ALT levels. (AI)

##### Hepatitis Screening

As part of the baseline assessment, clinicians should ask HIV-infected patients about their HBV vaccination history and should obtain the following serologic tests (AI):

- HBV serologies: hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs), and hepatitis B core antibody (anti-HBc) (immunoglobulin G [IgG] or total)
- Hepatitis A virus (HAV): IgG
- Hepatitis C virus (HCV): IgG

Clinicians should obtain an HBV deoxyribonucleic acid (DNA) test for patients with negative anti-HBs, negative HBsAg, and positive anti-HBc to determine whether the patient has occult HBV infection (see Figure 3 in the original guideline document). (AI)

Clinicians must report all suspected or confirmed hepatitis B infections, and specify acute or chronic, to the local health department of the area where the patient resides according to [New York State \(NYS\) requirements](#) (also see the [NYS Department of Health \[NYSDoH\] information for reportable communicable diseases](#)).

#### Prevention of HIV Infection: Vaccination and Post-Exposure Prophylaxis

##### Primary HBV Vaccination

Clinicians should:

- Administer the HBV vaccination series to HIV-infected patients who are negative for anti-HBs and are not chronically infected with HBV (see Figure 3 in the original guideline document) (AI)
- Test for anti-HBs 1 to 2 months after administration of the last dose of the vaccination series (AI)

##### *HBV Vaccination Strategies for HIV-Infected Patients*

If an accelerated HBV vaccination schedule of 0, 1, and 3 weeks is used for an HIV-infected patient, a fourth-dose booster should be administered at least 6 months after the initiation of the series. (AIII)

Clinicians should *not* administer the accelerated HBV vaccination schedule of 0, 1, and 3 weeks to patients with CD4 counts <500 cells/mm<sup>3</sup>. (AIII)

#### Key Points:

- Two HBV vaccination formulations are available in the United States (see Table 3 in the original guideline document). The efficacy of these vaccines has been reported to be equivalent when used in non-HIV-infected patients; however, equivalent effectiveness between

the two formulations has not been clearly established among HIV-infected patients.

- Because no data are available regarding double-dose or four-injection vaccination with the combined HAV and HBV vaccine (TWINRIX) in the presence of HIV, the combined vaccine is not recommended for double-dose or four-injection vaccination.
- Both Engerix B and RECOMBIVAX have received Food and Drug Administration approval for higher-strength regimens that are recommended in patients with end-stage renal disease (RECOMBIVAX: 1 mL of higher-strength 40 µg/mL formulation given in three intramuscular [IM] injections at 0, 4, and 24 weeks; Engerix B: 2 mL of 20 µg/mL vaccine in four IM injections at 0, 4, 8, and 24 weeks). These higher-strength regimens may also be considered for patients with other immunocompromising conditions.

Table 3 in the original guideline document provides dosing information on the two HBV vaccination formulations that are available in the United States.

#### HBV Re-Vaccination in HIV-Infected Nonresponders

HIV-infected patients who do not respond to the primary HBV vaccination series (anti-HBs <10 IU/L) should be re-vaccinated with a double-dose vaccination series (see Figure 3 in the original guideline document). (AII)

If a patient's CD4 count is <200 cells/mm<sup>3</sup> or the patient has symptomatic HIV disease:

- Re-vaccination may be deferred until several months after initiation of ART in an attempt to maximize the antibody response to the vaccine (BI)
- Re-vaccination should *not* be deferred in pregnant patients or patients who are unlikely to achieve an increased CD4 count (AIII)

#### Key Points:

- Patient education regarding HBV vaccination is important to ensure awareness of the continued risk of acquiring HBV until adequate surface antibody response is documented.
- Although one study of HIV-infected nonresponders demonstrated a re-vaccination response rate of up to 50% using a double dose of a 10-µg vaccine (HBvaxPro), this formulation is currently unavailable in the United States; therefore, a double dose of the 20-µg vaccine is recommended (see Table 3 in the original guideline for additional information).

#### HAV Vaccination

Clinicians should administer the HAV vaccine to HIV-infected patients who are negative for HAV IgG to prevent concurrent HAV infection (see the NYSDoH guideline [Hepatitis A Virus](#) [redacted]). (AI)

#### HBV Post-Exposure Prophylaxis

The HBV vaccination series plus hepatitis B immune globulin (HBIG) should be initiated in HIV-infected patients who sustain a blood or body fluid exposure and who are non-immune to HBV or who have unknown HBV immunity status at the time of presentation. (AI) Both HBIG and the first dose of the HBV vaccination series should ideally be administered within 24 hours of exposure (AII); HBIG should not be given later than 14 days post-exposure.

#### Evaluation of Patients with Chronic HBV

Clinicians should evaluate the extent of liver disease in patients with chronic HBV infection by:

- Obtaining an HBV-related history, including assessment for risk factors and previous signs and symptoms of advanced liver disease (AI)
- Performing a physical examination for current signs and symptoms of advanced liver disease (AI)
- Measuring serial ALT levels, prothrombin time/international normalized ratio (PT/INR), albumin, and platelet counts (AI)
- Assessing for inflammation, fibrosis, HBV replication, and risk of HCC
- Obtaining hepatitis B envelope antigen (HBeAg), hepatitis B envelope antibody (anti-HBe), and HBV DNA quantitative assay (nucleic acid amplification) (AI)
- Obtaining hepatitis delta virus (HDV) nucleic acid amplification or serologic assay if available (AIII)

If the baseline HBV DNA level is ≤2000 IU/mL in anti-HBe-positive patients with elevated serum ALT levels, then clinicians should perform serial HBV DNA measurements at least annually. (AIII)

Key Point:

Although seroconversion from HBeAg to anti-HBe is often associated with clinical improvement, greater HBV DNA replication and more rapid disease progression may occur in patients carrying mutations in either the precore or the basic core promoter region of the HBV genome.

Counseling for HIV/HBV Co-Infected Patients

Alcohol Consumption

Clinicians should educate HIV/HBV co-infected patients regarding the effects of alcohol on the course of HBV infection and should counsel patients with underlying liver disease to abstain from alcohol. (AI)

Clinicians should perform alcohol use screening for HIV/HBV co-infected patients as part of the baseline and annual substance use assessment (see the NYSDoH [Substance Use Screening Quick Reference Guide](#) [ ] and the guideline [Clinical Management of Alcohol Use and Abuse in HIV-Infected Patients](#) [ ]). (AI)

For HIV/HBV co-infected patients who screen positive for alcohol use, clinicians should:

- Administer a more detailed screening tool such as the full alcohol use disorders identification test (AUDIT) or CAGE (see the NYSDoH information on [Common Screening Tools for Identifying Substance and Alcohol Problems](#) [ ]) (AIII)
- Screen at-risk alcohol users every 3 months to determine whether intensified support, such as referral to an addiction provider, is required to reduce alcohol intake (AIII)
- Strongly encourage patients with alcohol abuse or dependence to enroll in a rehabilitation program (AI)

HBV Transmission

Clinicians should assess HBV transmission risk behaviors among patients who are positive for HBsAg and should:

- Encourage all sexually active HIV/HBV co-infected patients to use effective barrier protection consistently and correctly, including latex or polyurethane condoms and dental dams, to reduce the risk of transmission of HIV and HBV (AI)
- Advise household contacts of HBV carriers to be vaccinated for HBV and to avoid sharing objects that may be contaminated with blood, such as razors or toothbrushes, until their immunity has been confirmed (AI)

Clinicians should provide the following for all active injection drug users: (AI)

- Referral for substance use treatment
- Prescription of clean syringes and needles
- Referral to needle-exchange programs
- Education about safer-use practices (see the NYSDoH guideline [Working with the Active User](#) [ ])

Treatment and Management of HBV Infection in the Setting of HIV

Clinicians should strongly encourage HIV-infected patients with chronic HBV infection to initiate treatment for both viruses. (AII)

HIV/HBV co-infected patients should be educated about the importance of adherence to anti-HBV therapy once treatment is initiated and about risk of transaminase flares and hepatic damage resulting from treatment interruption that is not carefully monitored. (AI)

Clinicians should consider immune reconstitution inflammatory syndrome (IRIS) in HIV/HBV co-infected patients who experience acute elevations of transaminases after initiation of ART and/or anti-HBV therapy (see the NYSDoH guideline [Immune reconstitution inflammatory syndrome \[IRIS\] in HIV-infected patients](#) [ ]). (AIII)

Key Point:

Options for effective anti-HBV therapy are significantly increased when patients are treated concomitantly with ART.

## Treatment for Acute HBV Infection

Clinicians should consult with a provider experienced in the treatment of hepatitis and HIV when HIV-infected patients with acute HBV infection present with fulminant liver disease.

For HIV-infected patients with acute HBV infection who present with fulminant liver disease *and are receiving ART for HIV* (AI):

- The current anti-HIV therapy regimen should be adjusted to include lamivudine; tenofovir should be withdrawn if the patient is already receiving it until the hepatic insult has resolved
- Neither tenofovir *nor* adefovir should be prescribed until the hepatic insult has resolved

For HIV-infected patients with acute HBV infection who present with fulminant liver disease *and are not receiving ART for HIV* (AI):

- Initiation of ART for HIV is not recommended during fulminant hepatic liver disease until the acute hepatic insult has resolved
- Treatment with lamivudine alone is indicated for fulminant liver disease, despite the risk of developing lamivudine-resistant HIV; neither adefovir nor tenofovir should be prescribed until the hepatic insult has resolved.

## Treatment for Chronic HBV Infection

Clinicians treating HIV/HBV co-infected patients should:

- Initiate treatment with an ART regimen that contains two agents that are also active against the patient's HBV strain, including tenofovir plus either lamivudine or emtricitabine (AII)
- Consult with a provider experienced in the treatment of hepatitis and HIV to establish a schedule for monitoring (see Table 4 in the original guideline document) (AIII) and to discuss treatment decisions, including the following:
  - Changes to a patient's existing ART regimen (AIII)
  - Determination of an alternative anti-HBV regimen if first-line anti-HBV treatment with tenofovir plus lamivudine or emtricitabine cannot be prescribed because of HBV resistance to any of these agents or the presence of renal insufficiency or fulminant hepatic disease (AIII)
  - Treatment and monitoring for patients with cirrhosis (AII)
- Avoid discontinuation of either HBV or HIV treatment whenever possible and monitor serum ALT levels closely if discontinuation of anti-HBV therapy is unavoidable (AII)
- Obtain serum ALT level before initiation of ART or when changing the ART regimen (AII)

When ART regimens require a change for HIV considerations, the agents active against HBV should be continued whenever possible to avoid the risk of reactivation of HBV. (AII)

### Key Point:

The primary goal of anti-HBV therapy for HIV/HBV co-infected patients is HBsAg clearance with anti-HBs seroconversion. However, because the rate of anti-HBs seroconversion is low among HIV-infected patients and treatment should be considered lifelong once it is initiated, the following secondary goals are reasonable:

- HBeAg to anti-HBe seroconversion
- Suppression of HBV replication
- Reduction of liver inflammation
- Prevention or delay of progression of fibrosis, cirrhosis, and HCC

### Key Point:

Agents with dual activity against both HBV and HIV can simplify treatment regimens because these agents can be used as part of a regimen to treat both viruses.

## Treatment for HDV Infection

Clinicians should strongly encourage HIV/HBV/HDV tri-infected patients to initiate anti-HBV and anti-HIV therapy. (AIII)

#### Monitoring Patients with Chronic HBV Infection

After initiation of anti-HBV therapy, clinicians should obtain HBV DNA level and should assess for HBeAg and HBsAg seroconversion every 3 to 6 months. (AI)

Clinicians should obtain serum transaminase levels for HIV/HBV co-infected patients:

- Before initiation of ART or when changing the ART regimen (AII)
- Monthly for the first 3 months after initiation of ART to monitor for possible IRIS (see the NYSDoH guideline [Immune reconstitution inflammatory syndrome \(IRIS\) in HIV-infected patients](#) [redacted]) (AIII) *and*
- At least every 6 months thereafter (AII)

#### Key Points:

- Clinically relevant responses to anti-HBV therapy are a sustained seroconversion from HBsAg to anti-HBs, from HBeAg to anti-HBe, or normalization of ALT and sustained HBV DNA  $\leq 2000$  IU/mL.
- Lamivudine, entricitabine, and tenofovir generally should not be stopped as part of a patient's ART regimen when anti-HBV therapy is discontinued.

#### Patients with Cirrhosis

Patients with hepatitis who develop symptomatic cirrhosis should be managed by a clinician experienced in the management of cirrhosis in HIV/HBV co-infected patients, preferably a hepatologist. (AII)

Clinicians should refer HIV/HBV co-infected patients with known cirrhosis for endoscopy at least once every 2 years to monitor for esophageal varices. (AIII)

#### Key Point:

HIV/HBV co-infected patients with cirrhosis are at increased risk for a life-threatening hepatic flare due to IRIS after initiation of ART, particularly when their baseline CD4 count is  $<200$  cells/mm<sup>3</sup>.

#### Patients at Risk for HCC

##### *Risk Assessment for HCC*

Clinicians should assess for the risk of hepatocellular carcinoma in HIV-infected patients with chronic HBV according to standard guidelines (see Table 5 in the original guideline document).

##### *Surveillance for Patients at Risk for HCC*

Clinicians should perform surveillance for HCC among patients at high risk every 6 to 12 months according to the American Association for the Study of Liver Diseases (AASLD) standard guidelines. See Table 5 in the original guideline document to determine risk.

Serum  $\alpha$ -fetoprotein screening is no longer recommended as part of surveillance for HCC among patients at high risk. (AI)

#### Key Point:

Surveillance for patients at high risk for HCC involves standardized screening and monitoring protocols, as established by standard guidelines, such as the AASLD practice guidelines on the management of HCC.

#### Definitions:

## Quality of Evidence for Recommendation

- I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
- II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
- III. Expert opinion

## Strength of Recommendation

- A. Strong recommendation for the statement
- B. Moderate recommendation for the statement
- C. Optional recommendation

## Clinical Algorithm(s)

An algorithm titled "Algorithm for HBV Pre-Vaccination Screening and Vaccination in HIV-Infected Patients" is provided in the original guideline document.

## Scope

### Disease/Condition(s)

Human immunodeficiency virus (HIV) infection

### Other Disease/Condition(s) Addressed

- Hepatitis B
- Liver disease
- Substance-related disorders

## Guideline Category

Counseling

Evaluation

Management

Prevention

Screening

Treatment

## Clinical Specialty

Allergy and Immunology

Family Practice

Gastroenterology

Infectious Diseases

Internal Medicine

## Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

Substance Use Disorders Treatment Providers

## Guideline Objective(s)

To develop guidelines for the management of hepatitis B virus (HBV) infection in human immunodeficiency virus (HIV)-infected patients

## Target Population

Human immunodeficiency virus (HIV)-infected patients at risk for or co-infected with hepatitis B virus (HBV) infection

## Interventions and Practices Considered

### Evaluation/Screening/Prevention

1. Baseline hepatic function testing
2. Hepatitis screening:
  - Hepatitis B virus (HBV) vaccination history
  - HBV serologies including hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs), hepatitis B core antibody (anti-HBc) (immunoglobulin G [IgG] or total)
  - Hepatitis A virus (HAV): IgG
  - Hepatitis C virus (HCV): IgG
  - HBV deoxyribonucleic acid (DNA) test for patients with negative anti-HBs, negative HBsAg, and positive anti-HBc
  - Report all suspected or confirmed hepatitis B infections, and specify acute or chronic, to the local health department
3. Primary HBV vaccination:
  - HBV vaccination series in human immunodeficiency virus (HIV)-infected patients who are negative for anti-HBs and are not chronically infected with HBV
  - Testing for anti-HBs 1 to 2 months after vaccination
4. HBV re-vaccination in HIV-infected nonresponders
5. HAV vaccine in HIV-infected patients negative for HAV IgG
6. HBV post-exposure prophylaxis with HBV vaccination plus hepatitis B immune globulin (HBIG)
7. Evaluating the extent of liver disease in patients with chronic HBV infection:
  - HBV-related history, physical examination, and initial laboratory testing
  - Assessment for inflammation and fibrosis

### Management/Treatment

1. Counseling patients on the effects of alcohol consumption and HBV transmission
2. Lamivudine for patients with acute HBV accompanied by fulminant liver disease and are receiving antiretroviral therapy (ART) for HIV
3. Standard ART regimen that includes two drugs that are also active against HBV (e.g., tenofovir plus lamivudine or emtricitabine) for



HIV/HBV co-infected patients

4. Monitoring hepatic function in HIV/HBV co-infected patients who discontinue HBV treatment
5. Encouraging HIV/HBV/hepatitis delta virus (HDV) tri-infected patients to initiate anti-HBV and anti-HIV therapy
6. Referring patients with cirrhosis to a hepatologist
7. Surveillance of patients at risk for hepatocellular carcinoma (HCC) including screening serum alpha-fetoprotein and annual imaging (computed tomography [CT], magnetic resonance imaging [MRI], or ultrasound) at regular intervals
8. Monitoring treatment response

## Major Outcomes Considered

- Response rates to hepatitis B virus (HBV) vaccination and revaccination
- Risk for HBV infection
- Response rates to treatment of HBV infection
- Transmission rates of HBV infection
- Risk for immune reconstitution inflammatory syndrome (IRIS)
- Risk for hepatocellular carcinoma
- Development of drug resistance

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

The Medical Care Criteria Committee selects an expert author to revise the guideline; concurrent literature searches are conducted by guidelines program staff. All members of the Committee submit relevant literature to program staff and the author for review for the guideline revision.

For the current guideline update, the National Library of Medicine, PubMed Central, Cochrane Library, and MEDLINE databases were searched from 2007 to April 2013.

### Number of Source Documents

Not stated

### Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

Quality of Evidence for Recommendation

- I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints

- II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
- III. Expert opinion

## Methods Used to Analyze the Evidence

Review

## Description of the Methods Used to Analyze the Evidence

Not stated

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with human immunodeficiency virus (HIV) infection. Committees\* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees\* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

\*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection
- Committee for the Care of Substance Users with HIV Infection
- Physicians' Prevention Advisory Committee
- Pharmacy Advisory Committee

For the guideline on hepatitis B virus, the Medical Care Criteria Committee convened on October 28, 2011, March 16, 2012, March 25, 2012 (conference call), and March 5, 2012. The guideline draft is peer reviewed by 2 experts outside of the committee: the author incorporates any comments; the guideline is again reviewed by the Committee.

## Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

- A. Strong recommendation for the statement
- B. Moderate recommendation for the statement
- C. Optional recommendation

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

# Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

Once the revision is accepted by the committee, a guideline is reviewed by an internal New York State approval process. Any recommended changes are discussed with the author and the Committee to reach consensus, if needed.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Appropriate management of human immunodeficiency virus (HIV)-infected patients at risk for or co-infected with hepatitis B virus (HBV) infection

### Potential Harms

- Human immunodeficiency virus/hepatitis B virus (HIV/HBV) co-infected patients with cirrhosis are at increased risk for a life-threatening hepatic flare during immune reconstitution inflammatory syndrome (IRIS) after initiation of antiretroviral therapy (ART), particularly when their baseline CD4 count is  $<200$  cells/mm<sup>3</sup>. Clinicians should monitor transaminases during initiation of or changes to the ART regimen, especially in patients with cirrhosis.
- The alanine aminotransferase (ALT) levels frequently increase 1 to 2 months after lamivudine is started; this should not prompt discontinuation of the drug.
- Interferon-alfa has numerous side effects and toxicities that should be managed by a clinician experienced with its use.

## Contraindications

### Contraindications

- Because of the high concomitant rate of renal failure in fulminant hepatitis, neither adefovir nor tenofovir should be prescribed. Initiation of antiretroviral therapy (ART) should be deferred until resolution of the acute hepatic insult, including stabilization of liver function and associated complications, such as encephalopathy and coagulopathy. For patients with fulminant liver disease who are already receiving ART, the regimen should be adjusted to include lamivudine. Tenofovir should be withdrawn if the patient is already receiving it until the hepatic insult has resolved.
- Interferon-alfa cannot not be used in patients with decompensated cirrhosis.

## Qualifying Statements

### Qualifying Statements

When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.

## Implementation of the Guideline

### Description of Implementation Strategy

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

#### Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDoH) Distribution Center.

#### Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

### Implementation Tools

#### Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Living with Illness

Staying Healthy

## IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2013 Aug. 33 p. [79 references]

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2003 Mar (revised 2013 Aug)

### Guideline Developer(s)

New York State Department of Health - State/Local Government Agency [U.S.]

### Source(s) of Funding

New York State Department of Health

### Guideline Committee

Medical Care Criteria Committee

### Composition of Group That Authored the Guideline

*Medical Care Criteria Committee Chair:* Judith A Aberg, MD, FIDSA, FACP, ICAHN School of Medicine at Mount Sinai, New York, New York

*Medical Care Criteria Committee Vice-Chair:* Samuel T Merrick, MD, New York-Presbyterian Hospital, Weill Cornell Medical Center, New York, New York

*Medical Care Criteria Committee Members:* Bruce D Agins, MD, MPH, New York State Department of Health, AIDS Institute, New York, New York; James CM Brust, MD, Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, New York; Steven M Fine, MD, PhD, University of Rochester Medical Center, Rochester, New York; Luz Amarilis Lugo, MD, Mount Sinai Comprehensive Health Program, New York, New York; Joseph P McGowan, MD, FACP, North Shore University Hospital, Manhasset, New York; Neal Rzepkowski, MD, Erie County Medical Center, Buffalo, New York; Michael Serlin, MD, Harlem Hospital Center, New York, New York; Rona M Vail, MD, Callen-Lorde Community Health Center, New York, New York; Barry S Zingman, MD, Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, New York

*New York State Department of Correctional Services Liaisons:* Douglas G Fish, MD, Albany Medical College, Albany, New York; Carl J

Koenigsmann, MD, New York State Department of Correctional Services, Albany, New York

*Department of Veterans Affairs Medical Center Liaison:* Sheldon T Brown, MD, James J Peters Veteran Affairs Medical Center, Bronx, New York

*Medical Society of the State of New York Liaison:* William Valenti, MD, FIDSA, Trillium Health, Rochester, New York

*New York City Department of Health and Mental Hygiene Liaison:* Blayne Cutler, MD, PhD, New York City Department of Health and Mental Hygiene, Queens, New York

*New York City Health and Hospitals Corporation Liaison:* Carlos Salama, MD, Elmhurst Hospital Center, Elmhurst, New York

*HIV Quality of Care Advisory Committee Liaison:* Peter G Gordon, MD, Columbia University College of Physicians and Surgeons, New York, New York

*AIDS Institute Staff Liaison:* Gina M Brown, MD, National Institutes of Health, Bethesda, Maryland

*AIDS Institute Staff Liaison on STIs:* Demetre C Daskalakis, MD, Mount Sinai Comprehensive Health Program-Downtown, New York, New York

*AIDS Institute Staff Physicians:* Charles J Gonzalez, MD, New York State Department of Health, AIDS Institute, New York, New York; Cheryl A Smith, MD, New York State Department of Health, AIDS Institute, New York, New York

*Principal Investigator:* John G Bartlett, MD, Johns Hopkins University School of Medicine, Baltimore, Maryland

*Principal Contributor:* Steven M Fine, MD, PhD, University of Rochester Medical Center, Rochester

## Financial Disclosures/Conflicts of Interest

Committee by-laws and financial disclosures for committee members are available upon request at [jciekot@hivguidelines.org](mailto:jciekot@hivguidelines.org).

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2008 Jun. 23 p. [49 references]

## Guideline Availability

Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#) .

## Availability of Companion Documents

None available

## Patient Resources

None available

## NGC Status

This summary was prepared by ECRI on January 21, 2004. This NGC summary was updated by ECRI on October 19, 2005. This summary was updated by ECRI Institute on September 2, 2008. This summary was updated by ECRI Institute on March 13, 2014.

## Copyright Statement

This NGC summary is based on the original guideline, which is copyrighted by the guideline developer. See the [New York State Department of Health AIDS Institute Web site](#)  for terms of use.

## Disclaimer

### NGC Disclaimer

The National Guideline Clearinghouse<sup>SM</sup> (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the [NGC Inclusion Criteria](#).

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.